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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,835	06/23/2005	Kohji Kawahara	10936-88	2192

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EXAMINER	
HUANG, GIGI GEORGIANA	
ART UNIT	**PAPER NUMBER**
1612	

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06/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,835	KAWAHARA ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6,8-15 and 21-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6,8-15 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

Status of Application

1. The response filed January 19, 2010 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claims 2, 21, have been amended.

   b. Claim 23 has been added.

2. Claims 2-6, 8-15, 21-23 are pending in the case.

3. Claims 2-6, 8-15, 21-23 are present for examination.

4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.

5. All grounds not addressed in the action are withdrawn or moot.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 2-5, 8-15, 21-23 is rejected under 35 U.S.C. 102(b) as being anticipated by Tojo et al. (WO 01/26648).

It is noted that U.S. Pat. 7052714 will be used as the translation for WO 01/26648 and all references are to the U.S. Patent.

Tojo et al. teaches transdermal preparations comprising an adhesive with a drug

(plaster) with a release membrane, and a lining film (support). Drugs taught include anti-virals (e.g. acyclovir, ganciclovir) which is useful for ocular infection, and corticosteroids (e.g. prednisolone) an anti-inflammatory/antiallergic well known in the art to be useful for many conditions including conjunctivitis and uveitis (evidenced by Becker et al.). The patch comprises percutaneous absorption enhancer including polyoxyethylene oleyl ether, fatty acids, fatty acid esters, and higher alcohols at 5-30w/w.%; adhesives including acrylics (e.g. Nippon Carbide Industries PE-300, an alkyl (meth)acrylate-vinyl acetate copolymer), silicone base, or rubber base (e.g. styrene-isoprene-styrene copolymer) at 1-20wt.% and tackifier (e.g. thickeners, coagulation enhancers, paraffin); and the drug at 1-20wt.% which can be adjusted as desired based on the disease to be treated and its severity.

The patch can be applied to any desired body surface including the eyelid (see full document, specifically, Abstract, Col. 2 line 10-68, Col. 5 line 27-col. 7 line 40, col. 13 line 55- Col. 15 line 20, claim 7-10, 13-14, 16). Examples are presented where the general teaching for the patches has the components such as the acrylic, the enhancer, and the drug meet the claims. Example 2, 3, and 5 have the acrylic at 5.0 g (100parts, thereby 1 part is 0.05g), the enhancer is at 0.6g (12 parts), the drug is at 0.3g (6 parts-Ex.2), 0.45g (9 parts-Ex.3), and 0.3g (6 parts-Ex.5). General teaching in Example 11 for the styrene-isoprene-styrene patches have the styrene- isoprene-styrene at 0.9g (100parts, thereby 1 part is 0.009g),the isopropyl myristate enhancer is at 0.3g (33.3 parts),and the drug is at 0.15g (16.6 parts), the paraffin (tackifier) is at 0.15g (16.6 parts) meeting the claims. As for the permeation recitations, the effects of administering

the composition are inherent to the components of the composition and the mode of delivery. When the composition is delivered in the same manner as claimed, the effects of the composition would be the same such as penetration and the therapeutic profile, as they are a direct result of the components of the composition and the mode of administration which are met by the art whereby the resulting properties and effects would inherently be met as any component that materially affects the composition and its properties would have to be present in the claim to be commensurate in scope.

It is noted that the claims are reciting a method for transferring a remedy(drug) for ophthalmic diseases to an ophthalmic topical tissue comprising applying a transdermal drug delivery system comprising a plaster and a support, to the skin surface of an eyelid. However, transfer of the drug inherently occurs when a composition with the recited components (such as transdermal formulation) is applied to the cited mode of administration (applied to the skin of an eyelid). In fact, drug transfer is inherent to transdermal formulations by the nature of the art. Additionally, the amount of transfer and penetration would be inherent to the components of the composition and when delivered in the same manner as claimed, the effects of the composition would be the same such as the degree of penetration and drug delivery, as they are a result of the components of the composition and the mode of administration which are met by the art and the resulting properties and effects would inherently be met. It is also noted that the application of the patch as taught in Tojo would inherently treats anyone who may have the conditions recited as the drugs must pass through the eye (from anterior to posterior) and as the claims is not a method of treatment, but a method of transferring

a drug from the patch to the skin to tissue which as addressed above, is inherent to the application of transdermal devices by the nature of the art.

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 2-6, 8-15, 21-23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Higo et al. (U.S. Pat. 5866157) in view of Trimming et al. (U.S. Pat. Pub. 2001/0006968) in view of Tojo et al. (WO 01/26648) in view of Lerner et al. (WO 97/18855).

It is noted that U.S. Pat. 7052714 will be used as the translation for WO 01/26648 and all references are to the U.S. Patent.

Higo et al. teaches the use of a transdermal patch which has increased percutaneous absorbability of the drug and reduced irritation to the skin for the administration of active agents including ketotifen taught as a known antiallergic, with a reservoir and a support. Higo also teaches the patch to have an absorption enhancer, a hydrophobic high molecular material (adhesive), a tackifying resin, other components. The amount of active (e.g. ketotifen) is 0.1 to 20%, hydrophobic high molecular material is 15 to 65%, the tackifer is 10 to 70%, and the absorption enhancer is form 0.01 to

20%. The hydrophobic high molecular material can comprise styrene-isoprene-styrene block copolymers, isoprene rubber, and acrylic polymers such as copolymer of methacrylate, acrylic acid, and vinyl acetate. The absorption enhancer can comprise C6-C20 fatty acids, fatty alcohols, fatty acid esters or ethers, and other materials (see full document). There are examples of ketotifen matrix patches on a support (backing) wherein the amount of the components meet the claims such as Example 1: styrene-isoprene-styrene at 16.5% for Example 1 (100 parts/16.5g, 1 part=0.165g), tackifier-Alicyclic saturated hydrocarbon resin at 29.5% (178.8 parts), and ketotifen fumarate at 2% (12.1 parts); and Example 7: styrene-isoprene-styrene at 36.5% for Example 1 (100 parts/36.5g, 1 part=0.365g), tackifier-Alicyclic saturated hydrocarbon resin at 10% (27.4 parts), and ketotifen fumarate at 3.5% (9.59 parts)

Higo does not expressly teach an example with an acrylic polymer in the amounts claimed. Higo does teach that the hydrophobic high molecular material can comprise styrene-isoprene-styrene block copolymers, isoprene rubber, and acrylic polymers such as copolymer of methacrylate, acrylic acid, and vinyl acetate whereby these materials are taught to be functional equivalents. Higo also teaches that ketotifen is a known antiallergic with examples.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute the acrylic polymer for the styrene-isoprene-styrene block copolymers in the ketotifen examples presented as Higo teaches that these hydrophobic high molecular materials are functional equivalents. It is desirable for manufacturers to have analogous choices to substitute the hydrophobic high molecular

material when motivated by pricing, availability, or desired properties of the polymer such as the degree of adhesiveness, for the production of the final product.

Higo does not expressly teach placement on the eyelid. Higo does teach that ketotifen is a known antiallergic.

Timming et al. teaches that ketotifen (e.g. ketotifen fumarate) is useful for the treatment of allergic conjunctivitis, such as seasonal allergic conjunctivitis (see full document).

Tojo teaches that transdermal patches for ophthalmic conditions are known and can be applied to any body surface including the eyelid (Col. 7 line 35-40).

Lerner teaches that the skin of the eyelid has a resistance lower than that on the rest of the skin surface (Page 37 line 38- Page 38 line 1).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the ketotifen patch on the eyelid for its known use, as suggested by Timming, Tojo, and Lerner, and produce the instant invention. It would have been obvious to one of skill in the art as ketotifen is known in the art to be used for allergic conditions including allergic conjunctivitis and transdermal patches are known to provide safe continuous delivery as addressed by Higo, it would be obvious to use the transdermal patch for allergic conjunctivitis and place the patch as close to the eye as ocular transdermal patches are known as addressed by Tojo, and as it is taught by Lerner that the skin surface over the eyelid has less resistance that the rest of the skin of the body to provide not only direct deliver but more effective delivery as there is

better penetration from the lower resistance also providing motivation (improved delivery-lower resistance) for one of skill in the art to do so.

One of ordinary skill in the art would have been motivated to do this because it is desirable to provide better delivery of a known composition for a known treatment with a known method of administration with greater efficacy due to the lowered resistance of the eyelid. As for the recited permeation, when the composition is delivered in the same manner as claimed, the effects of the composition would be the same such as penetration and the therapeutic profile, as they are a direct result of the components of the composition and the mode of administration which are met by the art whereby the resulting properties and effects would intrinsically be met as any component that materially affects the composition and its properties would have to be present in the claim to be commensurate in scope.

It is noted that the transfer of a remedy (drug) intrinsically occurs when a composition with the recited components (such as transdermal formulation) is applied to the cited mode of administration (applied to the skin of an eyelid). In fact, drug transfer is intrinsic to transdermal formulations by the nature of the art. The claims are not a method of treatment but a method of transferring a drug from the patch to the skin to tissue which as addressed above is intrinsic to the application of transdermal devices by the nature of the art.

Double Patenting

8. Claim 2-5, 8-15, 21-23 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-7, 11, 48 of copending Application No. 10/569772 in view of Tojo et al. (WO 01/26648).

The claims of the conflicting application are drawn to the application of a muscarinic receptor agonist in a base matrix (acrylic, silicone, rubber adhesive) to the skin surface of the eyelid to promote lacrimal fluid secretion which is known to be useful for keratoconjunctivitis, a form of allergic conjunctivitis (see Wong et al.-Abstract) and would intrinsically treat the condition.

The conflicting claims do not recite a support. However, as taught by Tojo et al. it is obvious to add a support (lining film) to the base matrix as part of a transdermal delivery system to improve adhesion. As a result, the instant claim is obvious over the copending claims and encompasses the specific conflicting claims.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

9. Claim 2-5, 8-15, 21-22 is rejected under 35 U.S.C. 102(b) as being anticipated by Tojo et al. (WO 01/26648).

Applicant's arguments filed 1/19/2010 have been fully considered but they are not persuasive. Applicant's arguments are directed to methods of treatment and targeted treatment which is not commensurate in scope with the claims as addressed above. The instant claims are directed to a method of transferring a drug from the patch to the skin and tissue which as addressed above is inherent to the application of transdermal devices by the nature of the art. Tojo teaches the patch with the structural

components of the claimed patch and teaches its placement on the eyelid where the transfer of the drug to the skin and tissue are inherent. As for the permeation recitations, as addressed above the effects of administering the composition are inherent to the components of the composition and the mode of delivery. When the composition is delivered in the same manner as claimed, the effects of the composition would be the same as they are a direct result of the components of the composition and the mode of administration which are met by the art and any component that materially affects the composition and its properties would have to be present in the claim to be commensurate in scope.

Accordingly, the rejection is maintained.

10. Claim 2-6, 8-15, 21-22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Higo et al. (U.S. Pat. 5866157) in view of Trimming et al. (U.S. Pat. Pub. 2001/0006968) in view of Tojo et al. (WO 01/26648) in view of Lerner et al. (WO 97/18855).

Applicant's arguments filed 1/19/2010 have been fully considered but they are not persuasive. Applicant's arguments are directed to methods of treatment and targeted treatment which is not commensurate in scope with the claims as addressed above. The instant claims are directed to a method of transferring a drug from the patch to the skin and tissue which as addressed above is intrinsic to the application of transdermal devices by the nature of the art.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections

are based on combinations of references. Applicant argues that the drug form of Trimming is to eye drops verses the transdermal form of Higo which is not persuasive as the presentation of Trimming is merely to show the known use of ketotifen for allergic conjunctivitis and the argument that Tojo is indicates that eye drops are sufficient is inaccurate as Tojo is directed to applying transdermals to the eyelid for ophthalmic conditions and Lerner is merely to address that the eyelid is a desirable site for application as skin resistance is lower (better skin passage).

Accordingly, the rejection is maintained.

11. Claim 2-5, 8-15, 21-22 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-7, 11, 48 of copending Application No. 10/569772 in view of Tojo et al. (WO 01/26648).

Applicant's arguments filed 1/19/2010 have been fully considered but they are not persuasive. Applicant's arguments are that the copending and the instant application are distinct stating that the promotion of lacrimal fluid is not obvious over the method of transferring a remedy for ocular infection to external ophthalmic tissue comprising at least one of conjunctiva, lacrimal tissue and cornea, allergic conjunctivitis, pollinosis, vernal conjunctivitis, conjunctivitis, blepharitis, keratitis, corneal tumor, dacryocystitis, superficial keratitis, marginal blepharitis, scleritis, holdeolum, tarsadenitis, and trachoma. The argument is not persuasive as several of the conditions would benefit from the increased lacrimal secretion as recited in the copending application.

Conclusion

12. Claims 2-6, 8-15, 21-23 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GiGi Huang/
Examiner, Art Unit 1612
/Zohreh A Fay/
Primary Examiner, Art Unit 1612